Printing date 23.06.2015

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Version number 5

Revision: 08.05.2015

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- · 1.1 Product identifier
- Trade name: Harmony PF

• 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.

- · Application of the substance / the mixture Manufacture of dental prothesis
- 1.3 Details of the supplier of the safety data sheet
 Manufacturer/Supplier: Ivoclar Vivadent Inc.
 175 Pineview Drive, Amherst, N.Y. 14228 USA Tel. +1 800 533 6825 Fax +1 716 691 2285
- Further information obtainable from: Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein Regulatory Affairs sds@ivoclarvivadent.com
- · 1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

- Classification according to Regulation (EC) No 1272/2008 The product is not classified according to the CLP regulation.
- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008 Void

· Hazard pictograms Void

- · Signal word Void
- · Hazard statements Void
- Additional information:

Alloys do not require a label, providing they do not present a hazard to human health by inhalation, ingestion or contact with skin or to the aquatic environment in the form in which they are placed on the market. Safety data sheet available on request.

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- Description: Dental alloy

· Dangerous components:			
CAS: 7440-22-4	silver	substance with a Community workplace exposure limit	10-<25%
EINECS: 231-131-3			
CAS: 7440-50-8	copper	substance with a Community workplace exposure limit	3-<10%
EINECS: 231-159-6			
CAS: 7440-06-4	platinum	Ox. Sol. 2, H272	3-<10%
EINECS: 231-116-1			
(Contd. on page 2			td. on page 2)

Printing date 23.06.2015

Version number 5

Revision: 08.05.2015

Trade name: Harmony PF

• Additional information: For the wording of the listed risk phrases refer to section 16.

(Contd. of page 1)

SECTION 4: First aid measures

· 4.1 Description of first aid measures

- · General information: No special measures required.
- After inhalation:

Grinding dust: Supply fresh air; consult doctor in case of complaints.

In case of unconsciousness place patient stably in side position for transportation.

- *After skin contact:* After contact with the molten product, cool rapidly with cold water.
- After eye contact:

Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

Mechanical effects only.

- · After swallowing: Seek medical treatment.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed
- No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- Suitable extinguishing agents: The product is not flammable.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: Do not inhale explosion gases or combustion gases.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures Not required.

- · 6.2 Environmental precautions: No special measures required.
- 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

• 7.1 Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.

- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities

· Storage:

- · Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- Further information about storage conditions: None.
- 7.3 Specific end use(s) No further relevant information available.

(Contd. on page 3)

Printing date 23.06.2015

Version number 5

Revision: 08.05.2015

Trade name: Harmony PF

(Contd. of page 2)

SECTION 8: Exposure controls/personal protection

• Additional information about design of technical facilities: No further data; see item 7.

· 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

7440-22-4 silver

WEL Long-term value: 0.1 mg/m^3

7440-50-8 copper

WEL Short-term value: 2** mg/m³ Long-term value: 0.2* 1** mg/m³ *fume **dusts and mists (as Cu)

7440-06-4 platinum

WEL Long-term value: 5 mg/m³

• Additional information: The lists valid during the making were used as basis.

· 8.2 Exposure controls

· Personal protective equipment:

- General protective and hygienic measures: Usual hygienic measures for dental practice.
- Respiratory protection: Use respiratory protective device against the effects of fumes/dust/aerosol.
- *Protection of hands:* Protective gloves should always be worn during mechanical and thermal processing.
- · Material of gloves

Mechanical processing: Leather gloves Strong material gloves Thermal processing:

Heat protection gloves

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:

Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

9.1 Information on basic physical a General Information Appearance:	and chemical properties	
Form:	Solid	
Colour:	Yellow	
Odour:	Odourless	
Odour threshold:	Not determined.	
pH-value:	Not applicable.	
Change in condition		
Melting point/Melting range:	$900 - 940 \ ^{\circ}C$	
Boiling point/Boiling range:	Undetermined.	
Flash point:	Not applicable.	
Flammability (solid, gaseous):	Not determined.	
Self-igniting:	Product is not selfigniting.	

Printing date 23.06.2015

Version number 5

Revision: 08.05.2015

Trade name: Harmony PF

	(Contd. of pag
• Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not applicable.
· Density at 20 •C:	15.6 g/cm ³
Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with	
water:	Insoluble.
• Partition coefficient (n-octano	l/water): Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
Solids content:	100 %
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

- 10.2 Chemical stability Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: None under normal conditions of storage and use.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

- · Acute toxicity:
- · Primary irritant effect:
- on the skin: No irritant effect.
- on the eye: No irritating effect.
- · Sensitisation: No sensitising effects known.
- Additional toxicological information:

Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

SECTION 12: Ecological information

· 12.1 Toxicity

- Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.

(Contd. on page 5)

Printing date 23.06.2015

Version number 5

Revision: 08.05.2015

(Contd. of page 4)

Trade name: Harmony PF

• Additional ecological information:

· General notes: Generally not hazardous for water

· 12.5 Results of PBT and vPvB assessment

• **PBT:** Not applicable.

• **vPvB:** Not applicable.

• 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

· European waste catalogue

20 01 40 metals

· Uncleaned packaging:

· Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information · 14.1 UN-Number · ADR, ADN, IMDG, IATA Void · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA Void · 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class Void · 14.4 Packing group · ADR, IMDG, IATA Void · 14.5 Environmental hazards: · Marine pollutant: No · 14.6 Special precautions for user Not applicable. · 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable. · Transport/Additional information: Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). · UN ''Model Regulation'':

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The product is a medical device according to the Directive 93/42/EEC.

(Contd. on page 6)

[·] National regulations:

[•] Other regulations, limitations and prohibitive regulations

GB –

Printing date 23.06.2015

Version number 5

Revision: 08.05.2015

Trade name: Harmony PF

(Contd. of page 5)

• 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases

H272 May intensify fire; oxidiser.

- Abbreviations and acronyms:
- ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

Ox. Sol. 2: Oxidising Solids, Hazard Category 2

• * Data compared to the previous version altered.